from the device and applied to the skin would be absorbed by the skin, taken up by the various organs of the body, feeding them and effecting health; that ill health would result from malnutrition of color rays; that, by flooding color from the device over various specified areas of the body, various specified internal organs would be affected through the medium of the blood and nerves; that the important viscera may be caused either to dilate or contract by application to the skin of various colors of the spectrum; that various color combinations, depending upon the date of one's birth, would aid the body in distress; that red color emanating from the device would heal asthma, failing sight, deafness, lung and bronchial trouble, colds, chills, obesity, fatty degeneration of heart, low blood pressure, dropsy, loss of appetite, and nervousness; that orange color emanating from the device would effect restoration to normal function; that yellow color emanating from the device would effect restoration of digestive and tissue tone; that green color emanating from the devicewould be a tonic for nerves and digestion; that blue color emanating from the device would heal venereal diseases, pubic rashes, high blood pressure, boils, neuralgia, sciatica, lumbago, rheumatism, rheumatoid arthritis, osteoarthritis, skin eruptions, ulcers, fevers, circulatory disorders, hardening of the arteries, and toxemia; and that violet color emanating from the devicewould be anesthetic, relaxing, and uplifting.

PLEA: Nolo contendere.

Disposition: 4-18-55. Defendant sentenced to 90 days in jail.

4660. Vitozone ozone generator device. (F. D. C. No. 37281. S. Nos. 85-616/7 L.)

QUANTITY: 1 device at Sheridan, Wyo.

SHIPPED: During May or June 1954, from Billings, Mont., by Luther J. Martin. Accompanying Labeling: Booklets designated "Ozone God's Gift To Humanity No. 3 * * * by J. H. Effenberg" and "Better Health and Better Living," and leaflets designated "Vitozone The Only Ozone Generator with so many EXCLUSIVE practical features" and "Ozone Instructions."

Libeled: 10-8-54, Dist. Wyo.

CHARGE: 502 (a)—the accompanying labeling of the device when shipped contained false and misleading representations that the device was effective in the treatment of arthritis, nephrolithiasis, cholelithiasis, acute and chronic inflammatory conditions, asthma, diseased body cavities, including the pleural cavity, peritoneal cavity, bladder, urethra, intestines, impure blood, chlorosis, anemia, nervous prostration, tuberculosis of the skin, diphtheria, scarlet fever, infectious disease, tuberculosis, carbon monoxide poisoning, pneumonia, gas poisoning, whooping cough, amebic dysentery, Bright's disease, dropsy, and insomnia.

Disposition: 12-14-54. Default—destruction.

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N.				N. J. No.		
Adhesive bandages and adhesive		Anterior	pituitary	aqueous	ex-	
strips		b .				4645
Alpha tablets	4656		ovarian			4644
Androgenic substance	4655					

F11:

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4661-4680

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced or delivered for introduction into, or while in, interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or summary judgment; (2) criminal proceedings which were terminated upon pleas of nolo contendere or guilty and, in one case, upon a verdict of guilty; and (3) injunction proceedings in which decrees of injunction were entered upon default or consent of the defendants or after trial. The seizure proceedings are civil actions taken against the goods alleged to be in violation, and the criminal and injunction proceedings are against the firms or individuals charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, Commissioner of Food and Drugs. Washington, D. C., June 7, 1956.

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^{*}For omission of, or unsatisfactory, ingredients statements, see Nos. 4661, 4662, 4664; sale under name of another drug, No. 4673; failure to bear a label containing an accurate statement of the quantity of the contents, No. 4662; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 4662.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4661-4680

Adulteration, Section 501 (a) (2), the article had been held under insanitary conditions; Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its quality and purity fell below the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, and its quality fell below, that which it purported or was represented to possess; and, Section 501 (d), the article was a drug, and a substance had been (1) mixed with the article so as to reduce its quality or (2) substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient including the quantity, kind, and proportion of any alcohol contained therein; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; and, Section 502 (i) (3), the article was offered for sale under the name of another drug.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE

4661. Drug for treatment of stomach disorders, hyperacidity, and ulcers. (Inj. No. 166.)

COMPLAINT FOR INJUNCTION FILED: Between 2-5-48 and 3-25-48, Dist. Minn., against Joseph E. McCoy, Thief River Falls, Minn., to enjoin the interstate shipment of a misbranded drug consisting of a suspension of bismuth subnitrate in a solution of water, sugar, alcohol, pepsin, and orange flavoring material.

CHARGE: The complaint alleged that the defendant had been and still was introducing into interstate commerce the above-described drug, which was 'misbranded as follows:

- 502 (a)—the labeling represented that the drug was efficacious in the cure, mitigation, and treatment of stomach disorders, hyperacidity, and gastric ulcers, whereas it was not effective for such purposes;
- 502 (e)—the label of the drug failed to bear the common or usual name of each active ingredient, including the quantity, kind, and proportion of the alcohol contained therein; and.
- 502 (f) (1)—the labeling of the drug failed to bear adequate directions for use since the labeling contained no reference to the disease conditions for which the drug was intended.